

Please amend the application filed on even date herewith prior to proceeding with its examination.

IN THE CLAIMS

Please amend claims 4-6, 12, 13, 15, 18-21, 23-26, 28, 31-34, 36, 39-40, 48, 50 and 57, as follows:

4. (Amended) Biologically active isolated Tat protein, fragments thereof and/or mutants and/or Tat DNA according to [claims 1-3] claim 1 at amounts ranging between 10 ng/ml and 1  $\mu$ g/ml.

5. (Amended) Biologically active isolated Tat protein, fragments thereof and/or mutants and/or Tat DNA according to [claims 1-4] claim 1 for use in the prophylactic and/or therapeutic treatment of AIDS, tumors, syndromes and symptoms associated with HIV infection.

6. (Amended) Protein or peptide or DNA vaccine, prophylactic and/or therapeutic, against AIDS, AIDS-associated tumors, syndromes and symptoms associated with the HIV infection, comprising as active principle biologically active Tat and/or its mutants and/or portion of the protein or peptides or a DNA as defined in [claims 1-4] claim 1.

12. (Amended) Vaccine according to [claims 6-11] claim 6 comprising proteins or peptides conjugated with the T-helper universal epitope of Tetanus toxoid or any T-helper peptides.

A<sup>2</sup> cont  
13. (Amended) Vaccine according to [claims 6-12] claim 6 in combination with recombinant proteins or peptides of HIV Nef, Rev or Gag or part of them.

---

A<sup>3</sup>  
15. (Amended) Vaccine according to claim 6[-14] in combination with recombinant immuno-modulant cytokines or other molecules, or part of them, augmenting antiviral immune response.

---

18. (Amended) DNA vaccine according to claim[s] 6[,7, 9] comprising DNA encoding for Tat wild-type or its mutants or part of them, inserted in expression vectors.

19. (Amended) DNA vaccine according to claim[s] 6[,7, 9] in combination with an expression vector including HIV rev, nef and gag genes, or part of them.

A<sup>4</sup>  
20. (Amended) DNA vaccine according to claim[s] 18 [or 19] in which the vector is a plasmid co-expressing tat (wild-type or its mutants)/rev, tat (wild-type or its mutants)/nef, tat (wild-type or its mutants)/gag or part of them.

21. (Amended) DNA vaccine according to claim[s] 6[,7, 9] in combination with DNA molecules inserted in expression vectors encoding for immuno-modulant cytokines or other immuno-modulant molecules, or part of them, augmenting the antiviral immune response.

---

A<sup>5</sup>  
23. (Amended) DNA vaccine according to claim[s] 21 [or 22] in which the vector is a plasmid co-expressing tat (wild-type or its mutants)/IL-12, tat (wild-type or its mutants)/IL-15, tat (wild-type or its mutants)/other molecules, or part of them, able to augment the antiviral immune response.

24. (Amended) Vaccine according to claim[s] 18[-23] in which the vector is pCV0.

25. (Amended) Vaccine according to claim[s] 6[-24] including autologous dendritic cells treated and/or untreated according to the previous claims.

26. (Amended) Vaccine according to claim[s] 6[-25] including adjuvants able to augment the antiviral immune response.

28. (Amended) Vaccine according to claim[s] 6[-27] comprising systems for delivery.

31. (Amended) Vaccine according to claim[s] 29 [and 30] in which bacteria are modified to express viral antigens.

32. (Amended) Vaccine according to claim[s] 6[-31] for the immunization of peripheral blood cells from infected individuals, expanded by co-stimulation with magnetic beads coated with anti-CD3 and anti-CD28 antibodies.

33. (Amended) Therapeutic vaccine according to claim[s] 6[-32,] combined with inhibitors of viral replication.

34. (Amended) Vaccine according to claim[s] 6[-33] in which the active principle is delivered to the mucosa.

36. (Amended) Vaccine according to claim[s] 6[-33] in which the active principle is administered through systemic or local route.

39. (Amended) Vaccine according to claim[s] 34[-38] in which the active principle is carried in a biologically acceptable fluid.

40. (Amended) Vaccine according to claim[s] 34[-39] further comprising pharmaceutically acceptable carriers and [eccipients] excipients to maximize the principle activity.

910  
48. (Amended) Transformed cells including the vector according to claim[s] 45[-47].

911  
50. (Amended) Dendritic cells treated with Tat protein or its peptides or mutants according to claim[s] 43 [and 44] or combinations with Rev, Nef, and Gag proteins and/or cytokines.

912  
57. (Amended) Therapeutic method for treating AIDS, AIDS-associated tumors, syndromes and symptoms associated with HIV infection characterised in that preventive or therapeutic amounts of biologically active Tat according to claim[s] 1[-5] are administered.

0955534-073000  
Please cancel claims 41, 49, and 51-56, without prejudice or disclaimer.

Please add new claims 58-61, inclusive, as follows:

--58. Therapeutic method for treating AIDS, AIDS-associated tumors, syndromes and symptoms associated with HIV infection wherein the preventive or therapeutic amounts of biologically active Tat according to claim 1 are administered, being Tat in its non-oxidated and non-aggregated form.--

--59. Therapeutic method for treating AIDS, AIDS-associated tumors, syndromes and symptoms associated with HIV infection wherein the preventive or therapeutic amounts of biologically active Tat according to claim 1 are administered, Tat being lyophilized and re-suspended in a biologically acceptable fluid.--

--60. Therapeutic method for treating AIDS, AIDS-associated tumors, syndromes and symptoms associated with HIV infection wherein the preventive or therapeutic amounts of biologically active Tat according to claim 1 are administered in combination with Alum, ISCOM, RIBI and mixtures thereof.--